LAW OFFICES

DECHERT LLP

A PENNSYLVANIA LIMITED LIABILITY PARTNERSHIP 902 CARNEGIE CENTER, SUITE 500 PRINCETON, NJ 08540-6531 (609) 955-3200 ATTORNEYS FOR PLAINTIFFS BAXTER HEALTHCARE CORPORATION, BAXTER INTERNATIONAL INC., AND BAXTER HEALTHCARE S.A.

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

BAXTER HEALTHCARE CORPORATION, BAXTER INTERNATIONAL INC., and BAXTER HEALTHCARE S.A.,

Plaintiffs.

v.

HQ SPECIALTY PHARMA CORPORATION, WELGRACE RESEARCH GROUP, ESTATE OF GEORGE OWOO, and JANET FENNING-OWOO, in her capacity as INDEPENDENT ADMINISTRATOR OF THE ESTATE OF GEORGE OWOO and as VICE PRESIDENT OF WELGRACE RESEARCH GROUP,

Defendants.

Civil Action No. 13-cv-06228

SECOND AMENDED COMPLAINT

Plaintiffs Baxter Healthcare Corporation ("Baxter Healthcare"), Baxter International Inc. ("Baxter International"), and Baxter Healthcare S.A. ("Baxter HSA") (collectively, "Baxter"), by way of Amended Complaint against defendants HQ Specialty Pharma Corporation ("HQ Pharma"), Welgrace Research Group ("Welgrace"), the Estate of George Owoo ("Owoo Estate") and Janet Fenning-Owoo in her capacity as Independent Administrator of the Estate of George Owoo and as Vice President of Welgrace Research Group, allege as follows:

PARTIES

- 1. Plaintiff Baxter International is a corporation incorporated in Delaware, having its principal place of business at One Baxter Parkway, Deerfield, IL 60015.
- 2. Plaintiff Baxter Healthcare is a corporation incorporated in Delaware, having its principal place of business at One Baxter Parkway, Deerfield, IL 60015. Baxter Healthcare is a wholly owned subsidiary of Baxter International.
- 3. Plaintiff Baxter HSA is a corporation incorporated in Switzerland, having its principal place of business at Hertistrasse 2, Wallisellen, CH-8304, Switzerland. Baxter HSA is a wholly owned subsidiary of Baxter International.
- 4. Baxter is a global healthcare company that develops, manufactures and markets products for people with hemophilia, immune disorders, infectious diseases, kidney disease, trauma, and other chronic and acute medical conditions.
- 5. Upon information and belief, HQ Pharma is a corporation incorporated in New Jersey, having its principal place of business at 120 Route 17 North, Suite 130, Paramus, NJ 07652. HQ Pharma touts itself as a specialty pharmaceutical company that develops products for the hospital market.
- 6. Upon information and belief, Welgrace is a company having its principal place of business at the home of Owoo and Ms. Fenning-Owoo, 764 Porter Circle, Lindenhurst, Illinois 60046, prior to Owoo's death. Welgrace touts itself as having a pharmaceutical division dedicated to the development and commercialization of existing critical care/emergency products. George Owoo was the founder, President, and CEO of Welgrace.
- 7. It has been represented to Baxter that Welgrace is not formally incorporated or organized, and is not a validly existing legal entity. To the extent that Welgrace is not

incorporated or otherwise a validly existing legal entity, upon information and belief, Welgrace is the trade name of a business which was established, controlled, and owned by Owoo, which Owoo utilized for the purposes of providing consulting activities and for other business purposes; and Owoo conducted business as Welgrace, including entering into consulting agreements as Welgrace, submitting invoices from Welgrace, executing assignment agreements to Welgrace, and maintaining a website for Welgrace listing Owoo's home address as the principal place of business for Welgrace.

- 8. Upon information and belief, prior to his death, George Owoo resided with his wife, Janet Fenning-Owoo, at 764 Porter Circle, Lindenhurst, Illinois 60046. Ms. Fenning-Owoo filed for probate of the Estate of George Owoo on June 2, 2014, in Lake County Circuit Court, Waukegan, Illinios, Case No. 14P-00000496.
- 9. Upon information and belief, Janet Fenning-Owoo is the Independent
 Administrator of the Estate of George Owoo and the Vice President, Finance and
 Administration, of Welgrace. Upon information and belief, Ms. Fenning-Owoo formerly resided
 at 764 Porter Circle, Lindenhurst, Illinios 60046. Upon information and belief, Ms. FenningOwoo now resides in New Jersey.

NATURE OF ACTION

- 10. This is an action for infringement of United States Patent Nos. 6,310,094 ("the '094 Patent") and 6,528,540 ("the '540 Patent") (collectively, "the Patents-in-Suit") against HQ Pharma. This action is based upon the Patent Laws of the United States, 35 U.S.C. § 100, et seq.
- 11. This is also an action for misappropriation of trade secrets, tortious interference with contracts, tortious interference with prospective business relations, and unfair competition against HQ Pharma.

- 12. This is also an action to correct the named inventors of United States Patent Nos. 8,835,505 ("the '505 Patent") and 8,829,054 ("the '054 Patent) (collectively, "the '505 and '054 Patents") against HQ Pharma, Welgrace, Owoo Estate, and Ms. Fenning-Owoo in her capacity as Independent Administrator of the Owoo Estate and Vice President of Welgrace. This action is based upon 35 U.S.C. § 256.
- 13. This is also an action for declaratory judgment and/or to quiet title of the '505 and '054 Patents against HQ Pharma, Welgrace, Owoo Estate, and Ms. Fenning-Owoo in her capacity as Independent Administrator of the Owoo Estate and Vice President of Welgrace.

JURISDICTION AND VENUE

- 14. This Court has jurisdiction over the subject matter of the patent infringement action pursuant to 28 U.S.C. §§ 1331 and 1338(a), as well as 28 U.S.C. § 2201.
- 15. This Court has subject matter jurisdiction over the misappropriation of trade secrets, tortious interference with contracts, tortious interference with prospective business relations, and unfair competition claims against HQ Pharma under 28 U.S.C. § 1332, as there is complete diversity of citizenship between the parties and the amount in controversy exceeds \$75,000, exclusive of interest and costs. This Court also has supplemental jurisdiction over the misappropriation of trade secrets, tortious interference with contracts, tortious interference with prospective business relations, and unfair competition claims against HQ Pharma under 28 U.S.C. § 1367(a).
- 16. This Court has jurisdiction over the subject matter of the claim for correcting inventorship pursuant to 28 U.S.C. §§ 1331 and 1338(a).
- 17. This Court has supplemental jurisdiction over the claim for declaratory judgment and/or to quiet title under 28 U.S.C. § 1367(a).

- 18. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(b), 1391(c) and 1400(b).
- 19. This Court has personal jurisdiction over HQ Pharma because, *inter alia*, HQ Pharma is incorporated in this District and maintains its principal place of business in this District.
- 20. To the extent it exists as a validly existing legal entity, this Court has personal jurisdiction over Welgrace because, *inter alia*, upon information and belief, Ms. Fenning-Owoo is the Vice President of Welgrace and now resides in this District, and, upon information and belief, Ms. Fenning-Owoo's home is the principal place of business of Welgrace. Additionally, Welgrace regularly conducts business within this District because, *inter alia*, Welgrace conducts business and works with HQ Pharma which maintains its principal place of business in this District on the development of a generic version of Baxter's BREVIBLOC® Premixed Injection Products, and has thereby engaged in substantial and/or continuous and systematic contacts with this District, which satisfy due process and confer personal jurisdiction over Welgrace.
- 21. This Court has personal jurisdiction over the Owoo Estate because, *inter alia*, Ms. Fenning-Owoo is the Independent Administrator of the Owoo Estate and, upon information and belief, now resides in this District, and, prior to his death, Owoo engaged in substantial and/or continuous and systematic contacts with this District, including conducting business and working with HQ Pharma which maintains its principal place of business in this District in developing a generic version of Baxter's BREVIBLOC® Premixed Injection Products.

22. This Court has personal jurisdiction over Ms. Fenning-Owoo in her capacity as Independent Administrator of the Owoo Estate and Vice President of Welgrace because, *inter alia*, upon information and belief, Ms. Fenning-Owoo resides in this District.

THE DRUG APPROVAL PROCESS

- 23. A company seeking to market a new pharmaceutical drug in the United States must first obtain approval from the U.S. Food and Drug Administration ("FDA"), typically through the filing of a New Drug Application ("NDA"). *See* 21 U.S.C. § 355(a). The sponsor of the NDA is required to submit to FDA information on all patents claiming the drug that is the subject of the NDA, or a method of using that drug, and FDA then lists the patent information in its publication, the *Approved Drug Products with Therapeutic Equivalence Evaluations*, which is referred to as the "Orange Book." *See* 21 U.S.C. § 355(b)(1) and (c)(2).
- 24. Alternatively, a company may seek approval to market a new drug product by filing an NDA under 21 U.S.C. § 355(b)(2) (a "§ 505(b)(2) application") which refers to and relies in part on the safety and efficacy findings of a previously approved drug (referred to as a "reference listed drug"), typically one that was approved under an original NDA filed pursuant to 21 U.S.C. § 355(b)(1).
- 25. By allowing an applicant to piggy-back on the innovator company's investment in clinical or other studies relating to the previously approved, reference listed drug, the abbreviated § 505(b)(2) application process can provide a shorter and less costly drug development pathway for the applicant than exists for an applicant filing an original NDA.
- 26. In conjunction with this § 505(b)(2) application process, Congress has put in place a process for resolving patent disputes relating to § 505(b)(2) application products, pursuant to which a § 505(b)(2) applicant must provide certifications addressing each of the

patents listed in the Orange Book for the reference listed drug. *See* 21 U.S.C. § 355(b)(2)(A). *See also* 21 C.F.R. §§ 314.50(i), 314.54. The applicant may certify, for instance, that it believes a listed patent is invalid or will not be infringed by the manufacture, use, or sale of the § 505(b)(2) application product. *See* 21 U.S.C. § 355(b)(2)(A)(iv). *See also* 21 C.F.R. § 314.50(i)(1)(i)(A)(4). This is known as a "Paragraph IV Certification."

27. A § 505(b)(2) applicant that includes a Paragraph IV Certification with its application must also provide notice thereof to both the owner of the listed patents and the holder of the NDA for the referenced listed drug. This "Paragraph IV Notice" must include a detailed statement of the factual and legal bases supporting the § 505(b)(2) applicant's belief that the challenged patent is invalid or not infringed by the proposed § 505(b)(2) application product. *See* 21 U.S.C. § 355(b)(3). *See also* 21 C.F.R. § 314.52.

FACTUAL BACKGROUND

BAXTER'S PATENTS AND BREVIBLOC PRODUCTS

- 28. On October 30, 2001, the United States Patent and Trademark Office ("PTO") duly and legally issued the '094 Patent, entitled "Ready-to-Use Esmolol Solution," to Baxter International as assignee. A true and correct copy of the '094 Patent is attached as Exhibit A.
- 29. On March 4, 2003, the PTO duly and legally issued the '540 Patent, entitled "Esmolol Formulation," to Baxter International as assignee. A true and correct copy of the '540 Patent is attached as Exhibit B.
 - 30. Baxter International and Baxter HSA are the owners of the '094 and' 540 Patents.
- 31. On February 16, 2001, the FDA approved Baxter Healthcare's supplemental NDA No. 19-386/S-018 for BREVIBLOC® Premixed Injection (esmolol HCl in sodium chloride) in

2500mg/250mL IntraVia Containers, under § 505(b) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(b).

- 32. On January 27, 2003, the FDA approved Baxter Healthcare's supplemental NDA No. 19-386/S-020 for BREVIBLOC® Double Strength Premixed Injection (esmolol hydrochloride) 20 mg/mL in 100 mL Containers, under § 505(b) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(b) (collectively with the above BREVIBLOC® Premixed Injection (2500mg/250mL IntraVia Containers), "BREVIBLOC® Premixed Injection Products").
- 33. The BREVIBLOC® Premixed Injection Products are indicated, among other things, for the rapid control of heart rate in patients with atrial fibrillation or atrial flutter in perioperative, postoperative, or other emergent circumstances where short term control of heart rate with a short-acting agent is desirable.
- 34. Baxter Healthcare is the holder of the NDAs for each of the BREVIBLOC® Premixed Injection Products. It makes and sells the BREVIBLOC® Premixed Injection Products to hospitals and other healthcare providers, by exclusive license under the Patents-in-Suit, throughout the United States.
- 35. Plaintiffs jointly own all rights, title and interest in the Patents-in-Suit, including all rights needed to bring this action in Plaintiffs' names.
- 36. Baxter Healthcare submitted information regarding the '094 and '540 Patents to the FDA for listing in the Orange Book with respect to the BREVIBLOC® Premixed Injection Products. The FDA thereafter listed the '094 and '540 Patents in the Orange Book with respect to those products, pursuant to 21 C.F.R. § 314.53(e).

NAMED INVENTOR GEORGE OWOO'S INVOLVEMENT WITH ITS BREVIBLOC PRODUCTS

- 37. George Owoo ("Owoo") was employed by Baxter Healthcare from approximately March 1998 until his employment terminated in February 2010. He was previously employed by Ohmeda Pharmaceutical Products Division, Inc., which Baxter acquired in early 1998.
- 38. Upon being hired by Baxter, Owoo executed an Employment Agreement, on March 19, 1998. A true and correct copy of the Employment Agreement is attached as Exhibit C.
- Owoo from using any "Confidential Information" except during his employment with Baxter Healthcare and solely for the benefit of Baxter Healthcare. *See* Exhibit C at Paragraphs 3, 4. In addition, the Employment Agreement included a narrowly tailored non-competition obligation that forbade him from "render[ing] services, directly or indirectly, for a period of one year after termination of [his] employment with Baxter to any Competing Organization in connection with any Competing Product." *See id.* at Paragraph 5. The Employment Agreement further obligated him to assign to Baxter any inventions conceived or reduced to practice by him during the course of his employment at Baxter. *See id.* at Paragraphs 7-9.
- 40. During the course of his employment, Owoo was extensively involved in the research, development, engineering, and manufacture of Baxter's BREVIBLOC® Premixed Injection Products, as well as other products and potential products that contained esmolol hydrochloride, the active ingredient in Baxter's BREVIBLOC® Premixed Injection Products.

 Owoo was the technical lead for all BREVIBLOC® esmolol products at Baxter for many years leading up to his departure from Baxter. He was also involved with, and aware of, Baxter's

business and research plans and strategies regarding its BREVIBLOC® Premixed Injection Products and related research and development efforts.

- 41. Owoo is a named inventor on the Patents-in-Suit, and assigned his rights to the inventions set forth in those Patents to Baxter.
- 42. During the course of his employment with Baxter, and particularly in connection with his involvement in the research, development, engineering, and manufacture of the BREVIBLOC® Premixed Injection Products and related products and development projects, Owoo acquired Baxter's extensive, highly confidential information and trade secrets relating to those products and projects. This information includes, but is not limited to, formulation research and research reports, product test methods, API suppliers, API and finished product specifications, product stability profile, customers, medical and clinical strategy, clinical design, marketing and commercial strategies, competitive analyses, and new product development.
- 43. Baxter's success in the development and deployment of BREVIBLOC® Premixed Injection Products has been enabled by Baxter's trade secrets and confidential information. Baxter has invested substantial resources toward the research, development, marketing, and sale of BREVIBLOC® Premixed Injection Products. Baxter has a legitimate business interest in preserving the secrecy of its trade secrets and confidential information and in securing the ownership of its employees' inventions, discoveries, and other work product, all of which are essential to Baxter's continued mission of developing and deploying innovative esmolol hydrochloride-containing products for consumers.
- 44. Baxter has implemented numerous, comprehensive measures to protect its trade secret and confidential information from unauthorized use or disclosure. Among other things, Baxter (i) has employees sign an agreement at the inception of employment containing

noncompetition and nondisclosure provisions, (ii) maintains policies and procedures for the treatment of all confidential information, (iii) conducts routine employee training programs relating to the protection and nondisclosure of Baxter's trade secret and confidential information, (iv) undertakes significant efforts to protect its electronic information, including perimeter controls and internal controls, and (v) uses electronic security measures and uniformed security guards, as well as electronic security badges, to limit unauthorized access to Baxter's premises.

- 45. Baxter relied on Owoo's agreement to abide by the terms of the Employment Agreement and Owoo's obligations under the common law when it hired him and gave him access to its trade secret and confidential information, including information pertaining to all aspects of its portfolio of esmolol hydrochloride-containing products.
- 46. Owoo's employment with Baxter was terminated in February 2010. In connection therewith, Owoo entered into a Severance Agreement with Baxter, which he executed on February 14, 2010. A true and correct copy of the Severance Agreement is attached as Exhibit D.
- 47. Pursuant to the Severance Agreement, Baxter paid Owoo more than \$138,000 in severance, paid part of the cost of Owoo's medical and dental insurance premiums for six months, and provided other valuable consideration. *See* Exhibit D at Paragraphs 3(a) and 4(a).
- 48. In exchange, Owoo affirmed his agreement "to not disclose, use, or share any confidential, non-public information of the Company that [he] acquired during the course of his[] employment with the Company with/to any third party without the prior written consent of the General Counsel of the Company" (*id.*, at Paragraph 6(e)).
- 49. He also agreed "to honor and continue to abide by all obligations set forth in [his] Employment Agreement with the Company, which agreement is dated March 19, 1998 and

incorporated herein by reference as Exhibit A" (*id.* at Paragraph 6(f)). Those obligations included his nondisclosure and non-compete obligations.

50. He further agreed "to cooperate as reasonably necessary in any ongoing litigation, claim, investigation, or subpoena involving or relating to the Company for which [he] may, due to his/her prior employment with the Company, have knowledge" (*id.*, at Paragraph 6(g)). That same provision required that Owoo receive express written consent from Baxter before speaking to any third party regarding such "ongoing litigation, claim, investigation, or subpoena."

HQ PHARMA'S COMPETING GENERIC PRODUCT AND GEORGE OWOO'S INVOLVEMENT THEREWITH

- 51. Within a mere two months of his departure from Baxter but unbeknownst to Baxter Owoo and Welgrace (the consulting company Owoo founded and controlled) began working with HQ Pharma to develop a generic version of Baxter's highly successful BREVIBLOC® Premixed Injection Products. This conduct was in direct violation of his Severance and Employment Agreements and the common law.
- 52. Prior to September 5, 2013, HQ Pharma submitted to the FDA paperwork purporting to constitute a § 505(b)(2) application (No. 205-703), seeking approval to engage in the commercial manufacture, use, and sale of proposed Esmolol Hydrochloride Premixed Injection products in dosages of 2500mg/250mL (10mg/mL strength) and 2000mg/100mL (20 mg/mL strength) (collectively, "HQ Pharma Proposed Products"), referencing versions of Baxter's BREVIBLOC® Premixed Injection Products.
- 53. Owoo was involved in the development of the HQ Pharma Proposed Products from the outset and actively participated in the drafting of HQ Pharma's § 505(b)(2) Application No. 205-703. Upon information and belief, Owoo continued to consult with HQ Pharma concerning those Products until his sudden death on May 2, 2014.

- 54. Upon information and belief, during the course of his work with HQ Pharma, Owoo used and disclosed Baxter's highly valuable and competitively sensitive confidential information and trade secrets, to the detriment of Baxter and for the benefit of HQ Pharma.
- 55. The use and disclosure of that information provided significant competitive benefit to HQ Pharma in the development of its generic version of the BREVIBLOC® Premixed Injection Products, and if permitted by FDA to launch the HQ Pharma Proposed Products, that information will be highly useful to HQ Pharma in competing against Baxter in the marketplace.
- 56. Welgrace and HQ Pharma are "Competing Organizations" as that term is used in the Employment Agreement. The HQ Pharma Proposed Products are "Competing Products" as that term is used in the Employment Agreement.
- 57. On or about September 5, 2013, HQ Pharma sent Baxter Healthcare and Baxter International a notice stating that HQ Pharma had submitted its § 505(b)(2) application No. 205-703 seeking approval to manufacture, use, or sell the HQ Pharma Proposed Products prior to the expiration of the '094 and '540 Patents (the "HQ Pharma Paragraph IV Notice"). Baxter received the HQ Paragraph IV Notice on September 9, 2013.
- 58. The HQ Pharma Paragraph IV Notice advised Baxter that HQ Pharma's \$ 505(b)(2) application included a Paragraph IV Certification stating that it was HQ Pharma's opinion that the manufacture, importation, use, sale, or offer for sale of the HQ Pharma Proposed Products described in its \$ 505(b)(2) application No. 205-703 would not infringe any claim of the '094 Patent or the '540 Patent and/or that these patents were invalid.

GEORGE OWOO'S INVOLVEMENT WITH OTHER BAXTER RESEARCH AND DEVELOPMENT PROJECTS

59. During the course of his employment with Baxter, Owoo was also involved in and knowledgeable about research and development of esmolol hydrochloride formulations

containing propylene glycol and ethanol in flexible bag containers. Owoo was also extensively involved in the testing of formulations for stability to autoclaving. Owoo worked with other individuals at Baxter regarding the research, development, and testing of such formulations.

Owoo was also involved with, and aware of, Baxter's business and research plans and strategies regarding various formulations as well as related research and development efforts.

60. In his Employment Agreement with Baxter, Owoo agreed, *inter alia*, that "[a]ll Inventions related to the present or planned business of Baxter, which are conceived or reduced to practice by [Owoo], either alone or with others, during the period of [his] employment or during a period of one hundred twenty (120) days after termination of such employment, whether or not done during my regular working hours, are the sole property of Baxter." Exhibit C, ¶ 7. Owoo also agreed "to assign to Baxter or its nominee all my right, title, and interest in and to such Inventions." *Id.* at ¶ 8; *see also id.* at ¶ 9.

THE '505 AND '054 PATENTS

- On September 16, 2014, the PTO issued the '505 Patent, entitled "Ready-to-Use Co-Solvents Pharmaceutical Composition in Modified Flexible Plastic Container," from United States Patent Application No. 13/840,163 filed on March 15, 2013. The '505 Patent identifies Welgrace Research Group and HQ Specialty Pharma Corporation as assignees and lists George Owoo and Erica Castagna as the named inventors. A true and correct copy of the '505 Patent is attached as Exhibit E.
- 62. On September 9, 2014, the PTO issued the '054 Patent, entitled "Ready-to-Use Co-Solvents Pharmaceutical Composition in Modified Flexible Plastic Container," from United States Patent Application No. 13/973,003 filed on August 22, 2013, and claims priority to United States Patent Application No. 13/840,163 filed on March 15, 2013. The '054 Patent identifies

Welgrace Research Group and HQ Specialty Pharma Corporation as assignees and lists George Owoo and Erica Castagna as the named inventors. A true and correct copy of the '054 Patent is attached as Exhibit F.

- 63. Upon information and belief, the subject matter claimed in the '505 and '054 Patents, to the extent patentable, was developed at Baxter during Owoo's employment at Baxter and with the participation of Baxter. The issued claims of the '505 and '054 Patents recite and cover formulations and products developed and tested by Owoo and other Baxter employees while Owoo was employed at Baxter, and any difference between the formulations and products developed at Baxter and any of the claims in the '505 and '054 Patents, to the extent they are patentable, are insignificant in quality when measured against the dimension of the full invention. Upon information and belief, during the course of the development of formulations and products claimed in the '505 and '054 Patents, Owoo worked with other employees of Baxter testing the stability of the products to autoclaving.
- 64. Erica Castagna is not a true inventor of the subject matter claimed in the '505 and '054 Patents. The contributions of Erica Castagna to any of the claims of the '505 and '054 Patents for which she was named as an inventor, to the extent patentable, are insignificant in quality when measured against the dimension of the full claimed invention.

COUNT I (AGAINST HQ PHARMA) INFRINGEMENT OF THE '094 PATENT

- 65. Baxter incorporates each of the preceding paragraphs 1 to 64 as if fully set forth herein.
- 66. HQ Pharma's submission of § 505(b)(2) application No. 205-703 to the FDA, including the Paragraph IV Certification submitted therewith, which seeks FDA approval to engage in the commercial manufacture, use, and sale of the HQ Pharma Proposed Products prior

to the expiration of the '094 Patent, constitutes infringement of the '094 Patent under 35 U.S.C. § 271(e)(2)(A).

- 67. FDA has tentatively approved HQ Pharma's § 505(b)(2) application No. 205-703, and upon FDA granting final approval of that application, HQ Pharma will directly or indirectly infringe the '094 Patent under 35 U.S.C. § 271(a), (b) and/or (c) by engaging in the commercial manufacture, use, offer for sale, sale in and/or importation into the United States of the HQ Pharma Proposed Products, and/or by actively inducing and contributing to infringement of others engaging in such activities, unless this Court orders that the effective date of any FDA approval of HQ Pharma's § 505(b)(2) application is no earlier than the expiration date of the '094 Patent and any additional periods of exclusivity.
- 68. Baxter has no adequate remedy at law for HQ Pharma's infringement of the '094 Patent, and will be substantially and irreparably harmed by any such infringing activities unless those activities are enjoined by this Court.
- 69. HQ Pharma was aware of the existence of the '094 Patent as demonstrated by its reference to that patent in its § 505(b)(2) application, and, upon information and belief, was aware that the filing of its Paragraph IV Certification with respect to the '094 Patent constitutes infringement of that patent. This is an exceptional case within the meaning of 35 U.S.C. § 285.

COUNT II (AGAINST HQ PHARMA) INFRINGEMENT OF THE '540 PATENT

- 70. Baxter incorporates each of the preceding paragraphs 1 to 69 as if fully set forth herein.
- 71. HQ Pharma's submission of § 505(b)(2) application No. 205-703 to the FDA, including the Paragraph IV Certification submitted therewith, which seeks FDA approval to engage in the commercial manufacture, use, and sale of Proposed HQ Pharma Products prior to

the expiration of the '540 Patent, constitutes infringement of the '540 Patent under 35 U.S.C. § 271(e)(2)(A).

- 72. FDA has tentatively approved HQ Pharma's § 505(b)(2) application No. 205-703, and upon FDA granting final approval of that application, HQ Pharma will directly or indirectly infringe the '540 Patent under 35 U.S.C. § 271(a), (b) and/or (c) by engaging in the commercial manufacture, use, offer for sale, sale in and/or importation into the United States of the HQ Pharma Proposed Products, and/or by actively inducing and contributing to infringement of others engaging in such activities, unless this Court orders that the effective date of any FDA approval of HQ Pharma's § 505(b)(2) application is no earlier than the expiration date of the '540 Patent and any additional periods of exclusivity.
- 73. Baxter has no adequate remedy at law for HQ Pharma's infringement of the '540 Patent, and will be substantially and irreparably harmed by any such infringing activities unless those activities are enjoined by this Court.
- 74. Upon information and belief, HQ Pharma was aware of the existence of the '540 Patent as demonstrated by its reference to that patent in its § 505(b)(2) application, and was aware that the filing of its Paragraph IV Certification with respect to the '540 Patent constitutes infringement of that patent. This is an exceptional case within the meaning of 35 U.S.C. § 285.

COUNT III (AGAINST HQ PHARMA)

TORTIOUS INTERFERENCE WITH CONTRACT

- 75. Baxter incorporates each of the preceding paragraphs 1 to 74 as if fully set forth herein.
- 76. Baxter and Owoo are parties to the Severance Agreement and the Employment Agreement, which are valid and enforceable contracts.

- 77. Baxter performed all of its obligations under the Severance Agreement and the Employment Agreement.
- 78. Upon information and belief, HQ Pharma had actual or constructive knowledge of and/or should have known of Owoo's contractual obligations to Baxter, including but not limited to his non-disclosure, non-compete, and cooperation obligations.
- 79. Upon information and belief, HQ Pharma wrongfully, intentionally, with malice, and without justification and in reckless disregard for Baxter's contractual rights, interfered with Owoo's contractual obligations under the Severance Agreement and the Employment Agreement, and induced Owoo to breach the Severance Agreement and the Employment Agreement by having him perform work for a Competing Organization on a Competing Product (as those terms are defined in the Employment Agreement, which is incorporated by reference into the Severance Agreement), which work would further require and cause Owoo to use and/or disclose Baxter's confidential information.
- 80. Upon information and belief, HQ Pharma, in bad faith and with improper motive and/or means and in reckless disregard for Baxter's contractual rights, induced Owoo to breach his contractual obligations with Baxter.
- 81. Upon information and belief, as a result of the interference and inducement by HQ Pharma, Owoo breached the Severance Agreement and the Employment Agreement by failing to comply with several obligations in the Agreements, including but not limited to his non-disclosure, non-compete, and cooperation obligations.
- 82. Upon information and belief, by having Owoo work on esmolol hydrochloridecontaining Competing Products, HQ Pharma has used, and will continue to use, Baxter's

confidential information disclosed by Owoo in a manner that will cause substantial, immediate, and irreparable harm.

- 83. Upon information and belief, by having Owoo work on esmolol hydrochloride-containing Competing Products, there is a substantial risk that in the absence of appropriate injunctive relief, HQ Pharma will continue to use Baxter's confidential information disclosed by Owoo in a manner that will cause substantial, immediate, and irreparable harm.
- 84. As a direct and proximate result of HQ Pharma's interference, Baxter has suffered and/or will continue to suffer substantial irreparable harm and other damages.

COUNT IV (AGAINST HQ PHARMA)

TORTIOUS INTERFERENCE WITH PROSPECTIVE BUSINESS RELATIONS

- 85. Baxter incorporates each of the preceding paragraphs 1 to 84 as if fully set forth herein.
- 86. Baxter was, and will be, pursuing business and/or contractual relationships with customers for the sale of BREVIBLOC® Premixed Injection Products, which relationships will provide economic advantages to Baxter.
- 87. Given Baxter's position as the lone approved premixed esmolol hydrochloride-containing injection products (the BREVIBLOC® Premixed Injection Products), Baxter has a reasonable expectation of economic advantage by entering into valid business and/or contractual relationships with customers for the sale of BREVIBLOC® Premixed Injection Products.
- 88. Upon information and belief, HQ Pharma knows Baxter's expectations regarding its pursuit of business and/or contractual relationships with customers.
- 89. HQ Pharma seeks approval to market the HQ Pharma Proposed Products in competition with the BREVIBLOC® Premixed Injection Products.

- 90. Upon information and belief, if the FDA grants final approval of HQ Pharma Proposed Products, HQ Pharma will wrongfully, intentionally, with malice and without justification interfere with Baxter's reasonable expectations of economic advantage regarding potential business and/or contractual relationships.
- 91. As a direct and proximate result of the anticipated tortious interference with Baxter's reasonable expectations of economic advantage regarding potential business and/or contractual relationships upon HQ Pharma gaining approval to market the HQ Pharma Proposed Products, Baxter will suffer substantial irreparable harm and other damages. Further, without injunctive relief, HQ Pharma will continue to cause irreparable harm to Baxter.

COUNT V (AGAINST HQ PHARMA)

MISAPPROPRIATION OF TRADE SECRETS

- 92. Baxter incorporates each of the preceding paragraphs 1 to 91 as if fully set forth herein.
- 93. During the course of his employment, Owoo was exposed to numerous trade secrets of Baxter regarding the research, development, engineering, and manufacture of the BREVIBLOC® Premixed Injection Products, the research, development, engineering, and manufacture of other products and potential products containing esmolol hydrochloride, and Baxter's business and research plans and strategies regarding the BREVIBLOC® Premixed Injection Products and related research and development efforts. The trade secrets to which Owoo was exposed during his employment at Baxter include, but are not limited to, formulation research and research reports, product test methods, API suppliers, API and finished product specifications, product stability profile, customers, medical and clinical strategy, clinical design, marketing and commercial strategy, competitive analyses, and new product development.

- 94. These trade secrets derive their economic value from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from their disclosure or use.
- 95. These trade secrets were the subject of efforts that were reasonable under the circumstances to maintain their secrecy. Among other things, Baxter (i) has employees sign an agreement at the inception of employment containing noncompetition and nondisclosure provisions, (ii) maintains policies and procedures for the treatment of all confidential information, (iii) conducts routine employee training programs relating to the protection and nondisclosure of Baxter's trade secret and confidential information, (iv) undertakes significant efforts to protect its electronic information, including perimeter controls and internal controls, and (v) uses electronic security measures and uniformed security guards, as well as electronic security badges, to limit unauthorized access to Baxter's premises.
- 96. Upon information and belief, Owoo used and/or disclosed Baxter's trade secrets in developing esmolol hydrochloride products for HQ Pharma. Such use and/or disclosure is improper, as Owoo was bound both expressly and impliedly to maintain the secrecy of and to not use or disclose any of Baxter's trade secrets, and Owoo did not receive Baxter's consent to use or disclose Baxter's trade secrets.
- 97. Upon information and belief, HQ Pharma knew or should have known: (1) of Owoo's position at Baxter, (2) of the nature of the trade secrets he possessed by virtue of his position and length of employment with Baxter, and (3) that he used and disclosed Baxter's trade secrets in the course of his consulting and other work for HQ Pharma. Upon information and belief, HQ Pharma knew or should have known that any current or future use and/or disclosure of Baxter's trade secrets by Owoo would be improper.

- 98. Further, upon information and belief, HQ Pharma acquired Baxter's trade secrets by improper means because HQ Pharma knew or had reason to know that Owoo was breaching his confidentiality obligations to Baxter.
- 99. HQ Pharma has unlawfully and unjustly benefited from Owoo's use and/or improper disclosure to them of Baxter's trade secrets.
- 100. As a result of HQ Pharma's misappropriation, Baxter has suffered and/or will continue to suffer substantial, immediate and irreparable harm and damages.
- 101. Unless HQ Pharma is enjoined from further disclosing and/or using Baxter's trade secrets, Baxter will continue to suffer substantial, immediate and irreparable harm and damages.
- 102. Upon information and belief, the misappropriation of trade secrets by HQ Pharma was and continues to be willful and malicious.

COUNT VI (AGAINST HQ PHARMA) UNFAIR COMPETITION

- 103. Baxter incorporates each of the preceding paragraphs 1 to 102 as if fully set forth herein.
- 104. By engaging in the unlawful and improper conduct described above, HQ Pharma has engaged in unfair competition, with willful, wanton and reckless disregard for Baxter's rights.
- 105. As a result of HQ Pharma's unfair competition, Baxter has suffered and/or will continue to suffer substantial, immediate and irreparable harm and damages.
- 106. Unless HQ Pharma is enjoined from further unfair competition, Baxter will continue to suffer substantial, immediate and irreparable harm and damages.

COUNT VII (AGAINST HQ PHARMA)

UNJUST ENRICHMENT

- 107. Baxter incorporates each of the preceding paragraphs 1 to 106 as if fully set forth herein.
- 108. HQ Pharma's unlawful and improper conduct described above constitutes unjust enrichment.
- 109. By virtue of the unlawful and improper conduct described above, HQ Pharma has unjustly obtained and retained confidential and trade secret information of Baxter, the use and disclosure of which has provided significant competitive benefit to HQ Pharma in the development of its Proposed Products and its§ 505(b)(2) application, to the detriment of Baxter.
- 110. HQ Pharma has been unjustly enriched by the use of Baxter's confidential and trade secret information in the development of the HQ Pharma Proposed Products and its \$505(b)(2) application.
- 111. If permitted to launch the HQ Pharma Proposed Products, HQ Pharma will unjustly benefit from and be unjustly enriched by the misuse and misappropriation of Baxter's confidential and trade secret information. HQ Pharma will profit from the manufacture, sale, offer for sale, distribution, marketing, and advertisement of the HQ Pharma Proposed Products, which were developed and would be approved based on HQ Pharma's use of Baxter's confidential and trade secret information, all to the detriment of Baxter.
- 112. Permitting HQ Pharma to retain the benefits of the misuse and misappropriation of Baxter's confidential and trade secret information would violate fundamental principles of justice, equity and good conscience.
- 113. As a result of HQ Pharma's use of Baxter's confidential and trade secret information, Baxter has suffered and/or will continue to suffer substantial, immediate and irreparable harm and damages.

114. Unless HQ Pharma is enjoined from engaging in the commercial manufacture, use, and sale of the HQ Pharma Proposed Products, Baxter will continue to suffer substantial, immediate, irreparable, and unquantifiable harm and damages.

COUNT VIII (AGAINST HQ PHARMA, WELGRACE, OWOO ESTATE, AND MS. FENNING-OWOO)

CORRECTION OF INVENTORSHIP

- 115. Baxter incorporates each of the preceding paragraphs 1 to 114 as if fully set forth herein.
- 116. To the extent he is an inventor and to the extent the claims of the '505 and '054 Patents are patentable, the claims were conceived by Owoo while Owoo was working at Baxter. During his employment with Baxter, Owoo was involved in the research and development of esmolol hydrochloride formulations containing propylene glycol and ethanol in flexible bag containers. Owoo was also involved in the testing of the stability of such formulations to autoclaving.
- 117. Upon information and belief, Owoo used the information regarding formulations containing propylene glycol and ethanol in bag containers and stability to autoclaving that he obtained during the course of his employment at Baxter to claim the formulation and product as his own invention in the '505 and '054 Patents and as the property of HQ Pharma and Welgrace.
- 118. On March 15, 2013, HQ Pharma and Welgrace filed a patent application on an esmolol formulation including propylene glycol and ethanol in a bag container, naming Owoo and Erica Castagna as inventors. The application led to the issuance of the '505 Patent on September 16, 2014. On August 22, 2013, HQ Pharma and Welgrace filed a continuation application of the '505 application, naming Owoo and Erica Castagna as inventors. The continuation application led to the issuance of the '054 Patent on September 9, 2014.

- Patents, to the extent patentable, was developed at Baxter during Owoo's employment at Baxter and with the participation of Baxter. Issued claims of the '505 and '054 Patents recite and cover formulations and products developed and tested by Owoo and other Baxter employees while Owoo was employed at Baxter, and any difference between the formulations and products developed at Baxter and any of the claims in the '505 and '054 Patents, to the extent they are patentable, are insignificant in quality when measured against the dimension of the full invention. Upon information and belief, during the course of the development of formulations and products claimed in the '505 and '054 Patents, Owoo worked with other employees of Baxter testing the stability of the products to autoclaving.
- Owoo's position at Baxter, (2) of the nature of the confidential information regarding development and testing of esmolol hydrochloride formulations with propylene glycol and ethanol in flexible bags that Owoo possessed by virtue of his position and employment with Baxter, and (3) that Owoo used that confidential information in the course of his consulting and other work for HQ Pharma to obtain the claims in the '505 and '054 Patents. Upon information and belief, HQ Pharma knew or should have known that the claims of the '505 and '054 Patents, to the extent they are patentable, belong to Baxter.
- 121. Welgrace was aware of Owoo's obligations to Baxter under his Employment Agreement. Owoo founded Weglrace and acted as CEO and President, and Welgrace's principal place of business was Owoo's home address. Owoo and Welgrace are alter egos of each other, and Welgrace knew that the claims of the '505 and '054 Patents, to the extent they are patentable, belong to Baxter.

- 122. Upon information and belief, to the extent there is anything patentable in the '505 and '054 Patents, Erica Castagna's contributions to the inventions claimed in the '505 and '054 Patents are insignificant in quality when measured against the dimension of the full claimed invention, and the naming of Erica Castagna as an inventor on the '505 and '054 Patents was error on the part of HQ Pharma, Welgrace, and Owoo. There was no error on the part of Baxter in the naming of Erica Castagna as an inventor on the '505 and '054 Patents.
- 123. Therefore, this Court should order the Director of Patents to issue certificates correcting the '505 and '054 Patents to remove Erica Castagna as an inventor.

COUNT IX (AGAINST HQ PHARMA, WELGRACE, OWOO ESTATE, AND MS. FENNING-OWOO)

DECLARATORY JUDGMENT AND QUIET TITLE

- 124. Baxter incorporates each of the preceding paragraphs 1 to 123 as if fully set forth herein.
- 125. Baxter is the true titleholder to all right, title, and interest to the '505 and '054 Patents.
- 126. Upon information and belief, Erica Castagna is not a true inventor of any of the claimed inventions of the '505 and '054 Patents. Erica Castagna's contributions to the inventions claimed in the '505 and '054 Patents, to the extent patentable, are insignificant in quality when measured against the dimension of the full claimed invention.
- 127. To the extent there is anything patentable in the claims of the '505 and '054 Patents, Erica Castagna has no right, title or interest to any claims of the '505 and '054 Patents because she is not a true inventor of any of the claims. Nevertheless, Erica Castagna recorded assignment papers with the PTO, assigning the '505 and '054 Patents to Welgrace, the company founded by Owoo and at which Owoo acted as CEO and President, and HQ Pharma, the

company working with Owoo to develop generic versions of Baxter's BREVIBLOC® Premixed Injection Products.

- 128. The naming of Erica Castagna as an inventor on the '505 and '054 Patents and her recordation of assignment papers with the PTO which fail to reflect the true ownership rights in the '505 and '054 Patents constitutes a claim of inferior rights, title, interest to the '505 and '054 Patents, and such claim constitutes a cloud on Baxter's title.
- 129. To the extent Owoo is an inventor of anything patentable in the claims of the '505 and '054 Patents, Owoo conceived the claims while he was working at Baxter.
- all inventions conceived of during employment with Baxter, including the esmolol hydrochloride formulation containing propylene glycol and ethanol in flexible bag containers which is the subject matter claimed in the '505 and '054 Patents, to the extent such subject matter is patentable. Specifically, pursuant to Paragraph 7 of his Employment Agreement, Owoo agreed that "[a]ll Inventions related to the present or planned business of Baxter, which are conceived or reduced to practice by me, either alone or with others, during the period of my employment or during a period of one hundred twenty (120) days after termination of such employment, whether or not done during my regular working hours, are the sole property of Baxter." Exhibit C. Pursuant to Paragraph 8 of his Employment Agreement, Owoo agreed to "disclose promptly and in writing to Baxter, through [his] supervisor, all Inventions which are covered by this agreement" and "to assign to Baxter or its nominee all [his] right, title, and interest in and to such Inventions." Exhibit C.
- 131. To the extent there is anything patentable in the claims of the '505 and '054 Patents, Owoo could not have assigned any rights he had in the claims to an entity other than

Baxter because he lawfully assigned any such rights to Baxter during his employment with Baxter. Nevertheless, Owoo recorded assignment papers with the PTO, assigning the '505 and '054 Patents to HQ Pharma and Welgrace.

- 132. Welgrace was aware of Owoo's obligations to Baxter under his Employment Agreement. Owoo founded Weglrace and acted as CEO and President, and Welgrace's principal place of business was Owoo's home address. Owoo and Welgrace are alter egos of each other, and Welgrace knew that Baxter is the true titleholder to the claims of the '505 and '054 Patents, to the extent any such claims are patentable.
- 133. Upon information and belief, HQ Pharma knew or should have known of Owoo's employment by Baxter; HQ Pharma knew or should have known of Owoo's obligations to Baxter; HQ Pharma knew or should have known that Owoo conceived of the esmolol hydrochloride product containing propylene glycol and ethanol in flexible bag containers which is the subject matter claimed in the '505 and '054 Patents, to the extent patentable, while Owoo was employed by Baxter; and HQ Pharma knew or should have known that Baxter is the true titleholder to the claims of the '505 and '054 Patents, to the extent any such claims are patentable.
- 134. The assignment papers recorded with the PTO with respect to the '505 and '054 Patents fail to reflect the true ownership rights in the '505 and '054 Patents.
- 135. Owoo's recordation of assignment papers with the PTO with respect to the '505 and '054 Patents to Welgrace and HQ Pharma constitutes a claim of inferior rights, title, interest to the '505 and '054 Patents, to the extent there is anything patentable, and such claim constitutes a cloud on Baxter's title.

- 136. Baxter has and continues to sustain damages as a result of Erica Castagna, Welgrace, and HQ Pharma's wrongful cloud on the title of the '505 and '054 Patents.
- 137. Baxter will be irreparably harmed by Erica Castagna's improper claim to and assignment of the '505 and '054 Patents to Welgrace and HQ Pharma absent a judgment and/or quiet title that Baxter is the true titleholder of the '505 and '054 Patents, to the extent there is anything patentable.
- 138. Baxter will be irreparably harmed by Owoo's improper assignment of the '505 and '054 Patents to Welgrace and HQ Pharma absent a judgment and/or quiet title that Baxter is the true titleholder of the '505 and '054 Patents, to the extent there is anything patentable.
- 139. Therefore, Baxter is entitled to a declaratory judgment and/or quiet title that Baxter is the true titleholder of the '505 and '054 Patents, to the extent there is anything patentable.

PRAYER FOR RELIEF

WHEREFORE, Baxter respectfully requests the following relief:

- A. A judgment that, pursuant to 35 U.S.C. § 271(e)(2)(A), HQ Pharma has infringed the '094 Patent;
- B. A judgment that, pursuant to 35 U.S.C. § 271(e)(2)(A), HQ Pharma has infringed the '540 Patent;
- C. A declaration that HQ Pharma's commercial manufacture, use, offer for sale, sale in or importation into the United States of the Proposed HQ Pharma Products would infringe the '094 Patent;

- D. A declaration that HQ Pharma's commercial manufacture, use, offer for sale, sale in or importation into the United States of its Proposed HQ Pharma Products would infringe the '540 Patent;
- E. An order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any approval of HQ Pharma's NDA No. 205-703 and/or of the Proposed HQ Pharma Products shall not be earlier than the expiration date of the '094 and '540 Patents, including any extensions;
- F. A permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining HQ Pharma, its officers, agents, servants and employees, and those persons in active concert or participation with any of them (including without limitation Welgrace), from infringement of the '094 and '540 Patents for the full terms thereof (including any extensions), including without limitation, enjoining such persons from commercially making, using, selling, or offering to sell any of the Proposed HQ Pharma Products within the United States, or importing any such products into the United States, during the terms of those patents;
- G. An order that judgment be entered against HQ Pharma awarding Baxter monetary relief if HQ Pharma, its officers, agents, servants and employees, and those persons in active concert or participation with any of them (including without limitation Owoo and Welgrace), commercially makes, uses, sells, offers for sale in, or imports into, the United States, any of the Proposed HQ Pharma Products prior to the expiration of the '094 and '540 Patents for the full terms thereof (including any extensions), and that any such monetary relief be awarded with prejudgment interest;
- H. A permanent injunction restraining and enjoining HQ Pharma, its officers, agents, servants and employees, and those persons in active concert or participation with any of

them (including without limitation Welgrace), from seeking, obtaining or maintaining final approval of HQ Pharma's 505(b)(2) application No. 205-703 until expiration of the '094 and '540 Patents;

- I. A permanent injunction restraining and enjoining HQ Pharma, its officers, agents, servants and employees, and those persons in active concert or participation with any of them (including without limitation Welgrace), from commercially making, using, selling, or offering to sell any of the Proposed HQ Pharma Products within the United States, or importing any such products into the United States, during the terms of the '094 and '540 Patents;
- J. A declaration that this is an exceptional case and an award of reasonable attorneys' fees pursuant to 35 U.S.C. § 285 and all other relevant statutes against HQ Pharma;
- K. An order preliminarily, and then permanently, enjoining HQ Pharma, its officers, agents, servants and employees, and those persons in active concert or participation with any of them (including without limitation Welgrace) from relying on, using, and/or disclosing to anyone or any entity, any of Baxter's confidential information and trade secrets;
- L. An order preliminarily, and then permanently, enjoining HQ Pharma, its officers, agents, servants and employees, and those persons in active concert or participation with any of them (including without limitation Welgrace) from retaining any documents, materials or information in their possession, custody or control relating to Owoo's employment with Baxter, including any of Baxter's confidential information and trade secrets;
- M. An order requiring HQ Pharma to disgorge any profits derived from the manufacture, use, sale, or offer for sale of any of the Proposed HQ Pharma Products, or from any other use of any confidential or trade secret information of Baxter;

- N. A judgment that Erica Castagna is not a joint inventor of the '505 and '540 Patents;
- O. An order that the Director of Patents issue a certificate correcting the named inventors of the '505 and '540 Patents by removing Erica Castagna;
- P. A declaration that Erica Castagna, HQ Pharma, the Owoo Estate, and Welgrace have no right, title, or interest in the '505 and '054 Patents, to the extent there is anything patentable, and quieting title in the '505 and '054 Patents to Baxter;
- Q. To the extent necessary to evidence Baxter's ownership, an order requiring HQ, Welgrace and/or the Owoo Estate to execute and deliver a legally sufficient assignment document that evidences Baxter's right, title, and interest to the '505 and '054 Patents;
 - R. An award of attorneys' fees against HQ Pharma;
 - S. Costs and expenses in this action against HQ Pharma; and
 - T. Such other and further relief as the Court may deem just and proper.

DECHERT LLP

Dated: January 16, 2015 /s/ Robert D. Rhoad

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ATTORNEYS FOR PLAINTIFFS BAXTER HEALTHCARE CORP., BAXTER INTERNATIONAL INC., AND BAXTER HEALTHCARE S.A.

CERTIFICATION OF NON-ARBITRABILITY

Pursuant to Local Civil Rule 201.1 (d)(2), the undersigned attorney for plaintiffs Baxter

Healthcare Corporation, Baxter International Inc., and Baxter Healthcare S.A. certifies that this

action is not eligible for compulsory arbitration under Local Civil Rule 201.1 because the relief

sought in the Complaint primarily consists of a demand for preliminary and permanent injunctive

relief, and because if HQ Pharma were to commercially make, use, sell, offer for sale in, or

import into the United States any of the Proposed HQ Pharma Products prior to the expiration of

the '094 and '540 Patents, Baxter's monetary damages would exceed \$150,000.

LOCAL CIVIL RULE 11.2 CERTIFICATION

Pursuant to Local Civil Rule 11.2, the undersigned attorney for plaintiffs Baxter

Healthcare Corporation, Baxter International Inc., and Baxter Healthcare S.A. certifies that to the

best of his knowledge, the matter in controversy is not the subject of another action pending in

any court or of any pending arbitration or administrative proceeding.

DECHERT LLP

Attorneys for Plaintiffs

Baxter Healthcare Corporation,

Baxter International Inc., and

Baxter Healthcare S.A.

Dated: January 16, 2015

By:

/s/ Robert D. Rhoad Robert D. Rhoad

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